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April 2006

To: Ambulance Service Providers

Ambulance Service Medical Directors

EMS Training Centers EMS Coordinators

From: Dan Williams, Chief

Wisconsin Emergency Medical Services Systems Section

Bureau of Local Health Support and EMS

Re: Pandemic Flu Information

There has been much discussion in the media regarding Pandemic Flu and more specifically Bird Flu. Much of what has been discussed is speculation. It is not the intent of this memo to provide you with an all encompassing plan for all aspects of what may or may not happen or what you should do or not do as an EMS service provider in preparation if this type of catastrophic event should occur. The intent is for you to become aware that EMS will likely play a significant role as part of this situation and there are some common sense precautions and preparations that should be considered.

I have attached two documents to this memo.

The first document is from Centers for Disease Control and Prevention (CDC) and is titled; **Emergency Medical Services and Non-Emergent (Medical) Transport Organization Pandemic Influenza Planning Checklist.** This checklist is design for you to conduct a self assessment of how you currently stack up in preparation and it will also show you where more work may be needed.

The second document is **General Questions and Answers to Prepare for Pandemic Influenza and Other Communicable Diseases.** This document is prepared based on information provided by CDC and provides questions and answers about safety precautions to avoid contracting and spreading these communicable diseases.

As further information becomes available and changes are made we will make every effort to keep the EMS community informed. It is my hope that this will provide you with some initial information so that you can prepare your service and personnel to react in a safe, effective and organized response to the citizens of your communities. Additional information is available at www.cdc.gov/flu/.

As with all communicable diseases, the best defense is a strong infection control program consisting of the <u>precautionary use</u> of PPE including masks, gloves and gowns.

EMERGENCY MEDICAL SERVICE AND NON-EMERGENT (MEDICAL) TRANSPORT ORGANIZATIONS PANDEMIC INFLUENZA PLANNING CHECKLIST

Planning for pandemic influenza is critical for ensuring a sustainable health care response. The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) have developed the following checklist to help emergency medical services (EMS) and non-emergent (medical) transport organizations assess and improve their preparedness for responding to pandemic influenza. EMS organizations will be involved in the transport of acutely ill patients with known or suspected pandemic influenza to emergency departments; some of these patients might require mechanical ventilation for life support and/or other lifesaving interventions. Non-emergent (medical) transport organizations will be called upon to transport recovering pandemic influenza patients to their home, residential care facility, or possibly to alternate care sites set up by state or local health departments. This checklist is modeled after one included in the HHS Pandemic Influenza Plan (www.hhs.gov/pandemicflu/plan/sup3.html#app2). The list is comprehensive but not complete; each organization will have unique and unanticipated concerns that also will need to be addressed as part of a pandemic planning exercise. Also, some items on the checklist might not be applicable to all organizations. Collaborations among hospital, public health and public safety personnel are encouraged for the overall safety and care of the public. Further information can be found at www.pandemicflu.gov.

This checklist identifies key areas for pandemic influenza planning. EMS and non-emergent (medical) transport organizations can use this tool to self-assess and identify the strengths and weakness of current planning. Links to websites with information are provided throughout the document. However, actively seeking information that is available locally or at the state level will be necessary to complete the development of the plan. Also, for some elements of the plan (e.g., education and training programs), information may not be immediately available and monitoring of selected websites for new and updated information will be necessary

1	Structure	for n	lanning	and a	decision	making
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Completed	In Progress	Not Started	
			Pandemic influenza has been incorporated into emergency management planning and exercises for the organization.
			A planning committee ¹ has been created to specifically address pandemic influenza preparedness.
			A person has been assigned responsibility for coordinating pandemic influenza preparedness planning (hereafter referred to as the pandemic response coordinator) for the organization. (Insert name, title, and contact information.)
			Members of the planning committee include the following: (Insert below or attach a list with name title and contact information for each.)
			Administration:
			Medical staff:
			EMS providers:
			Phone triage personnel/dispatch center:
			Emergency management officer:
			State/local health official:
			Law enforcement official (for quarantine/security):
			Other member ² :
			A point of contact (e.g., internal staff member assigned infection control responsibility for the organization or an outside consultant) for questions/consultation on infection control has been identified. (Insert name, title, and contact information.)
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^{1.} Size of committee can vary, depending on the size and needs of the organization.

^{2.} Some organizations may need or want to include a school official or volunteer coordinator for local civic and preparedness groups (e.g., Medical Reserve Corps, Citizen Corps, Community Emergency Response Teams, Rotary Club, Lions, Red Cross).

2. Devel	opment of	a written	pandemic influenza plan.
Completed	In Progress	Not Started	
			Copies of relevant sections of the Department of Health and Human Services Pandemic Influenza Plan have been obtained. www.hhs.gov/pandemicflu/plan .
			Copies of available community and state pandemic plans have been obtained.
			A written plan has been completed or is in progress that includes the elements listed in #3 below.
			The plan describes the organizational structure (i.e., lines of authority) that will be used to operationalize the plan.
			The plan complements or is part of the community response plan.
3. Eleme	ents of an i	influenza p	pandemic plan.
Completed	In Progress	Not Started	
			A plan is in place for surveillance and detection of pandemic influenza in the population served and the appropriate organizational response.
			Responsibility has been assigned for monitoring national and state public health advisories (e.g., www.cdc.gov/flu/weekly/fluactivity.htm) and informing the pandemic response coordinator and members of the pandemic influenza planning committee when cases of pandemic influenza have been reported in the United States and when they are nearing the geographic area (e.g., state or city). (Insert name, title, and contact information of person responsible.)
			A system has been created to track influenza-like illness in patients transported to hospitals and among EMS staff and to report this information to the pandemic response coordinator (i.e., weekly or daily number of patients with influenza-like illness). For more information see www.cdc.gov/flu/professionals/diagnosis/ . (Having a system for tracking illness trends in patients and staff during seasonal influenza will ensure that organizations can detect stressors that may affect operating capacity, such as staffing and supply needs, and hospital and emergency department capacity during a pandemic.)
			A communication plan has been developed.
			Key public health points of contact for pandemic influenza have been identified. (Insert below or attach a list with the name, title, and contact information for each.)
			Local health department contact:
			State health department contact:
			Local emergency management contact:
			State emergency management contact:
			Federal health emergency contact(s):
			The organization's point person for external communication has been assigned. (Insert name, title, and contact information.)
			(Having one person who speaks with the health department, and if necessary, media, local politicians, etc., will help ensure consistent communication is provided by the organization.)
			A list of healthcare entities and their points of contact (e.g., other local EMS and non-emergent [medical] transport organizations, local hospitals and their emergency departments, community health centers, residential care facilities has been created. (Insert location of or attach copy of contact list.)
			The pandemic response coordinator has contacted local or regional pandemic influenza planning groups to obtain information on communication and coordination plans, including how EMS will be represented in the planning process. (For more information on state and local planning, see www.hhs.gov/pandemicflu/plan/part2.html#overview .)
			The pandemic response coordinator has contacted other EMS and non-emergent (medical) transport organizations regarding pandemic influenza planning and coordination of services.

3. Eleme	ents of an i	influenza j	pandemic plan. (continued)
Completed	In Progress	Not Started	
			A plan is in place to ensure that education and training on pandemic influenza is provided to ensure that all personnel understand the implications of, and control measures for, pandemic influenza and the current organization and community response plans.
			A person has been designated to coordinate education and training (e.g., identify and facilitate access to education and training programs, ensure that staff attend, and maintain a record of attendance at education and training programs). (Insert name, title, and contact information.)
			Current and potential opportunities for long-distance (e.g., web-based) and local (e.g., health department or hospital sponsored programs, programs offered by professional organizations or federal agencies) education of EMS and medical transport personnel have been identified. (For more information see www.cdc.gov/flu/professionals/training/ .)
			Language and reading-level-appropriate materials for professional and non-professional personnel on pandemic influenza (e.g., available through state and federal public health agencies and professional organizations) have been identified and a plan is in place for obtaining these materials.
			Education and training include information on infection control measures to prevent the spread of pandemic influenza.
			Differences between responding to pandemic influenza and a mass casualty event have been incorporated into education and training programs.
			A plan has been developed for triage and management of patients during a pandemic that includes the following:
			A system for phone triage of patients calling 911 or other emergency numbers that might be used (provide/post list of appropriate numbers) that includes pre-established criteria and coordination protocols to determine who needs emergency transport. The system includes points of referral for patients who do not need emergency transport.
			A plan for coordination with receiving facilities (e.g., hospital emergency departments), other EMS and non-emergent (medical) transport organizations, and local planning groups to manage the transportation of large numbers of patients at the height of the pandemic.
			A policy and procedure for transporting multiple patients with pandemic influenza during a single ambulance run.
			The plan considers the possible necessity of sharing transportation resources or using vehicles other than those designed for emergency or medical transport (e.g., buses).
			An infection control plan is in place and includes the following: (For information on infection control recommendations for pandemic influenza, see www.hhs.gov/pandemicflu/plan/sup4.html).
			A plan for implementing Respiratory Hygiene/Cough Etiquette for patients with a possible respiratory illness.
			The plan includes distributing masks ³ to symptomatic patients who are able to wear them (adult and pediatric sizes should be available), providing facial tissues and receptacles for their disposal, and hand hygiene materials in EMS and medical transport vehicles.
			Implementation of Respiratory Hygiene/Cough Etiquette has been exercised during seasons when seasonal influenza and other respiratory viruses (e.g., respiratory syncytial virus, parainfluenza virus) are circulating in communities.
			A policy that requires healthcare personnel to use Standard Precautions (www.cdc.gov/ncidod/dhqp/glisolation_standard.html) and Droplet Precautions (i.e., mask for close contact) (www.cdc.gov/ncidod/dhqp/glisolation_droplet.html) with symptomatic patients.

^{3.} Masks include both surgical and procedure types. Procedure masks that are affixed to the head with ear loops might be used more easily by patients and are available in pediatric and adult sizes. Either surgical or procedure masks may be used as a barrier to prevent contact with respiratory droplets.

3. Elements of an influenza pandemic plan. (continued) **Not Started** Completed In Progress An occupational health plan has been developed that includes the following: A liberal/non-punitive sick leave policy for managing EMS and non-emergent (medical) transport personnel who have symptoms of, or documented illness with, pandemic influenza. The policy considers the following: • Handling of staff who become ill at work. • When personnel may return to work after recovering from pandemic influenza. • When personnel who are symptomatic but well enough to work will be permitted to continue working. • Personnel who need to care for their ill family members. A system for evaluating symptomatic personnel before they report for duty that has been tested during a non-pandemic influenza period. A list of mental health and faith-based resources available to provide counseling to personnel during a pandemic. Management of personnel who are at increased risk for influenza complications (e.g., pregnant women, immunocompromised healthcare workers) by placing them on administrative leave or altering their work locations. The ability to monitor seasonal influenza vaccination of personnel. Offering annual influenza vaccine to personnel. A vaccine and antiviral use plan has been developed. Websites containing current CDC and state health department recommendations for the use and availability of vaccines and antiviral medications have been identified. (For more information, see www.hhs.gov/pandemicflu/plan/sup6.html and www.hhs.gov/pandemicflu/plan/sup7.html.) An estimate has been made of the number of personnel who will be targeted as first and second priority for receipt of pandemic influenza vaccine and antiviral prophylaxis, based on HHS guidance for use. (For more information, see www.hhs.gov/pandemicflu/plan/appendixd.html.) Discussions have been held with the local and/or state health department regarding the role of the organization in a large-scale program to distribute vaccine and antivirals to the general population. Concerns related to surge capacity during a pandemic have been addressed. A plan is in place for managing a staffing shortage within the organization because of illness in personnel or their family members. The minimum number and categories of personnel necessary to sustain EMS and non-emergent (medical) transport services on a day-to-day basis have been determined. Contingency staffing plans have been developed in collaboration with other local EMS and nonemergent (medical) transport providers. Hospitals and regional planning groups have been consulted regarding contingency staffing resources. Anticipated consumable resource needs (e.g., masks, gloves, hand hygiene products) have been estimated. A primary plan and contingency plan to address supply shortages have been developed. These include detailed procedures for the acquisition of supplies through normal channels and requesting resources for replenishing supplies when normal channels have been exhausted. Plans include stockpiling at least a week's supply of resources when evidence exists that pandemic influenza has reached the United States. An understanding of the process exists for requesting and obtaining assets for the organization made available through the community response plan.

GENERAL INFORMATION (INCLUDING QUESTIONS AND ANSWERS) TO PREPARE FOR PANDEMIC FLU AND OTHER COMMUNICABLE DISEASES

Q. What is personal protective equipment?

A. Personal protective equipment is any type of specialized clothing, barrier product, or breathing (respiratory) device used to protect workers from serious injuries or illnesses while doing their jobs.

Centers for Disease Control and Prevention (CDC) recommends that healthcare workers wear the following personal protective equipment during the care of a patient with suspected or confirmed flu (influenza):

- surgical masks
- medical gloves
- surgical gowns

For more information about CDC's recommendations for controlling the spread of the flu, see http://www.cdc.gov/flu/.

Q. How does personal protective equipment help prevent the spread of infection?

A. Personal protective equipment acts as a barrier between infectious materials and the skin, mouth, nose, or eyes (mucous membranes). This equipment:

- protects healthcare workers from infection or contamination from blood, body fluids, or respiratory secretions;
- reduces the chance that healthcare workers will infect or contaminate others; and
- reduces the chance of transmitting infections from one person to another.

Q. How is personal protective equipment for healthcare workers different from personal protective equipment used in other job settings?

A. Personal protective equipment for healthcare workers is regulated by the Food and Drug Administration (FDA). FDA sets performance criteria for each product and makes sure that the manufacturers follow certain performance standards.

FDA does not regulate personal protective equipment used outside of healthcare settings.

For more information on personal protective equipment, see "Personal Protective Equipment in Patient Care" below.

Q. Will personal protective equipment cleared by FDA protect against bird flu (avian influenza)?

A. All personal protective equipment cleared by FDA must be able to block the passage of small particles the size of most infectious materials. However, FDA does not ask manufacturers to test the equipment with any particular disease or disease-causing agent (pathogen). Thus neither FDA nor a manufacturer can say for sure that this equipment will protect against bird flu.

Q. How do I know if personal protective equipment is cleared by FDA?

A. The FDA's <u>www.accessdata.fda.gov/scripts/cdrh/devicesatfda/</u> website lets you search for medical devices that FDA has cleared or approved, including personal protective equipment. You can search for:

- all FDA-cleared surgical masks
- all FDA-cleared gloves
- all FDA-cleared gowns

Q. Will personal protective equipment protect me from infection when caring for a sick person at home?

A. CDC (and not FDA) determines what personal protective equipment is appropriate under each different condition. For more information about CDC's recommendations for controlling the spread of the flu, see http://www.cdc.gov/flu/.

Q. Should medical offices keep an extra supply of masks, medical gloves, or gowns in reserve in case of a flu outbreak?

A. When deciding whether or not to keep personal protective equipment in reserve, you should consider

- your normal usage patterns.
- how those patterns might change in the event of a flu outbreak; and
- how difficult it would be for you to find supplies if your existing supplier could not deliver your supplies as quickly as usual.

Personal protective equipment (PPE)

PPE is any type of specialized clothing, barrier product, or breathing (respiratory) device used to protect workers from serious injuries or illnesses while doing their jobs. When caring for patients, PPE helps

- protect against infection or contamination from blood, body fluids, or respiratory secretions;
- reduce the chance that healthcare workers will infect or contaminate patients or coworkers;
- prevent the chance of transmitting infections from one person to another;
 and
- protect against harmful chemicals or other hazards surrounding the patient.

When to use PPE

Use PPE to cover the face, hands, other exposed skin, and clothing during patient care activities that may cause exposure to body fluids (such as blood, respiratory secretions, vomit, urine or feces), or chemicals.

This type of PPE can also be used in other job settings where workers could be exposed to similar hazards.

How to know what types of PPE to use

CDC (the Centers for Disease Control and Prevention), and not FDA, recommends what personal protective equipment is appropriate for caring for patients with transmissible infections. For more information about CDC's recommendations for PPE see http://www.cdc.gov/flu/.

Avoid Reusing PPE

Do NOT reuse personal protective equipment. Almost all personal protective equipment is designed to be used one time for one patient. Dispose of the equipment carefully after each patient use or if the equipment becomes soiled.

The only type of personal protective equipment that can be reused is a surgical gown that is labeled as washable for multiple use.

Washing and disinfecting PPE

The only type of personal protective equipment that can be washed is a surgical gown that is labeled as washable for multiple use.

There is no proper way to wash or disinfect **disposable** personal protective equipment. Dispose of the equipment carefully after each patient use or if the equipment becomes soiled.

Sharing PPE

Do NOT share personal protective equipment. Used equipment will not provide an effective barrier against hazards or infection.

Disposing of contaminated PPE at healthcare and public facilities

The FDA does not regulate the disposal of PPE. The following are general recommendations. Please refer to the EPA's medical waste website at http://www.epa.gov/epaoswer/other/medical/, OSHA's bloodborne pathogens and

needlestick prevention website at

http://www.osha.gov/SLTC/bloodbornepathogens/index.html, and individual State websites for specific requirements regarding the disposal of contaminated PPE.

PPE that is dripping with blood or body fluids (grossly contaminated) should be placed into a container that is leak-proof and closed. If the outside of the container becomes contaminated, it should be placed into a second similar container. Waste containers must be marked with either a biohazard symbol such as the one shown below, or placed in a colored-coded container such as a red bag.



Lightly soiled PPE, for example PPE with spots of blood or with small amounts of body fluids absorbed into the materials, can be discarded in the regular trash. Waste containers holding contaminated PPE are considered to be Biohazardous medical waste which needs to be disposed of according to individual state regulations.

There are no additional requirements for disposing of PPE from patients in isolation. Follow the same methods and procedures as for any other medical waste.

Disposing of contaminated PPE at home

When disposing of PPE at home,

- always wear medical gloves;
- place used or soiled PPE into a tied plastic bag to prevent dripping;
- carefully clean waste containers with disinfectant or diluted bleach (1 part bleach to 9 parts water); and
- wash hands thoroughly with soap and water or alcohol-based hand rub after handling.

About surgical masks and surgical N-95 respirators

Surgical masks and surgical N-95 respirators are disposable devices that cover the mouth and nose during medical procedures. They help protect the caregiver and patient against microorganisms, body fluids, and small particles in the air.

Surgical masks and surgical N-95 respirators are regulated by the Food and Drug Administration (FDA). FDA makes sure that manufacturers of these devices meet performance criteria such as fluid resistance, filtration efficiency, etc.

Respirators are also regulated and certified by NIOSH. When a mask is both cleared by FDA as a surgical mask and certified by NIOSH as an N-95 respirator mask, FDA calls it a "surgical N-95 respirator."

When to use surgical masks and surgical N-95 respirators

Use surgical masks and surgical N-95 respirators to cover your mouth and nose when you may be splattered by or exposed to someone else's body fluids (such as blood, respiratory secretions, vomit, urine or feces).

Types of masks and respirators used in patient care

Surgical masks

- include masks labeled as surgical, laser, isolation, dental, or medical procedure masks
- protect against microorganisms, body fluids, and large particles in the air
- designed to cover the mouth and nose loosely; not sized for individual fit
- protect patients from exposure to the wearer's saliva and respiratory secretions
- made of soft materials and are comfortable to wear
- usually packaged in boxes of single-use masks

Surgical N-95 respirators

- surgical masks that are designed to protect against small droplets of respiratory fluids and other airborne particles in addition to all the protection of surgical masks
- closely fit to form a tight seal over the mouth and nose
- must be fit-tested and adjusted to your face
- may be uncomfortable due to tight fit
- usually packaged as single devices or in boxes of single-use devices

Choosing between surgical masks and N-95 surgical respirators

CDC recommends the use of surgical masks or surgical N-95 respirators based on the ways that specific diseases are transmitted.

Choose a surgical mask to

- protect yourself if you may be splattered by someone else's body fluids (such as blood, respiratory secretions, vomit, urine or feces).
- protect others if you are performing surgery, are caring for an open wound, or if you are sick.

Choose a surgical N-95 respirator to

 protect yourself if you will be exposed to very small particles such as fine aerosolized droplets such as those produced by coughing. care for persons with known or suspected pulmonary and laryngeal tuberculosis. (OSHA requires that healthcare workers wear surgical N-95 respirators when caring for patients with known or suspected pulmonary and laryngeal tuberculosis.)

Non-medical N-95 respirators

There are N-95 respirators and other similar respirators available for various occupational exposures that do not make medical claims and are not regulated by FDA. These respirators are available from many sources including hardware stores and online. They are rated based on the size of the particles they can filter in industrial settings. Many of these respirators are intended to filter out particles of dust and mist from wood, metal, and masonry work.

What you should know before using surgical masks and surgical N-95 respirators

- Fit surgical N-95 respirators properly. A surgical N-95 respirator that has
 not been fitted properly may have unprotected gaps between the
 respirator and your face. Facial hair or unusual facial features make it
 difficult to fit surgical N-95 respirators properly.
- Be aware that surgical masks are not fit-tested to your face and may leave unprotected gaps between the mask and your face.
- Wear goggles or glasses with side shields if your surgical masks do not include eye protection.
- Be aware that masks lose their protective properties and must be changed when they become wet from saliva or respiratory secretions.
- Know that surgical masks and surgical N-95 respirators are not tested against specific microorganisms and should not claim to prevent specific diseases.
- See CDC recommendations for using surgical masks and surgical N-95 respirators in the care of patients needing isolation precautions.
- Never reuse surgical masks or surgical N-95 respirators.
- Never wash or disinfect surgical masks or surgical N-95 respirators.
- Never share surgical masks or surgical N-95 respirators with others.

About medical gloves

Medical gloves are disposable gloves used during medical procedures. Medical gloves help prevent contamination between caregivers and patients. Some are designed to prevent contact with certain chemotherapy drugs.

Medical gloves include examination gloves, surgical gloves, and medical gloves for handling chemotherapy agents (chemotherapy gloves). These gloves are regulated by the Food and Drug Administration (FDA). FDA makes sure that manufacturers of these devices meet performance criteria such as leak resistance, tear resistance, etc.

When to use medical gloves

Use medical gloves when your hands or nails may touch someone else's body fluids (such as blood, respiratory secretions, vomit, urine or feces) or certain hazardous drugs.

What you should know before using medical gloves

- Wash your hands before putting on sterile gloves.
- Make sure your gloves fit properly for you to wear them comfortably during all patient care activities.
- Some people are allergic to the natural rubber latex used in some medical gloves. FDA requires manufacturers to identify on the package labeling the materials used to make the gloves. If you are allergic to natural rubber latex, you should choose gloves made from other synthetic materials (such as polyvinyl chloride (PVC), nitirole, or polyurethane).
- Be aware that sharp objects can puncture medical gloves.
- Always change your gloves if they rip or tear.
- After removing gloves, wash your hands thoroughly with soap and water or alcohol-based hand rub.
- Never reuse medical gloves.
- Never wash or disinfect medical gloves.
- Never share medical gloves with other users.

About surgical gowns

Surgical gowns are garments worn during medical procedures. Gowns help prevent contamination between caregivers and patients, and they protect the caregiver's clothing.

Surgical gowns, which also include isolation gowns, are regulated by the Food and Drug Administration (FDA). FDA makes sure that manufacturers of these devices meet performance criteria such as penetration resistance, tear resistance, etc.

When to use surgical gowns

Use surgical gowns to cover your trunk, arms, legs, and clothing when you may be splattered by someone else's body fluids (such as blood, respiratory secretions, vomit, urine or feces).

Types of gowns used in patient care

Surgical gowns

Usually packaged as sterile products or designed to be sterilized

- Some are disposable and others are made of fabric that is labeled as washable for multiple use
- Come in various sizes, including one-size-fits-all
- Made of fluid-resistant materials to reduce the transfer of body fluids

Isolation gowns

- not sold as sterile products
- usually intended to protect the wearer from the transfer of microorganisms and only small amounts of body fluids

Choosing between surgical gowns and isolation gowns

When working in a hospital or other healthcare environment, follow your facility's standards of practice for wearing surgical gowns.

- Choose a surgical gown when performing surgery or other sterile procedure.
- Choose an isolation gown when caring for a patient in isolation.

What you should know before using surgical gowns

- Select gown materials based on the activity and the amount of body fluid that is expected.
- · Remove surgical gowns promptly when they are soiled.
- If blood or body fluids soak through a surgical gown, remove it and any soiled clothing underneath and immediately wash skin.
- Never reuse disposable surgical gowns.
- Never wash or disinfect disposable surgical gowns.
- Never share surgical gowns with other users.

Find all FDA-cleared surgical gowns

FDA's <u>www.accessdata.fda.gov/scripts/cdrh/devicesatfda/</u> website lets you search for medical devices that the FDA has cleared or approved, including personal protective equipment.